RESPONSE

The Office Action mailed September 2, 2004 has been carefully considered. Reconsideration in view of the following remarks is respectfully requested.

Claims 1-17 are currently pending. Claims 1-17 have been rejected. Claims 1 and 5 have been amended to further particularly point out and distinctly claim subject matter regarded as the invention. Support for these changes may be found in the specification on pages 9, 11 and 19. The text of claims 2-4 and 6-17 are unchanged, but their meaning is changed because they depend from amended claims. No new matter has been added.

The specification was amended for clerical matters. No new matter has been added.

Record of Interview

On December 1, 2004, an interview was conducted by telephone between Examiner Isis Ghali, Adrienne Yeung Reg. No. 44,000, and Co-Inventor Eduardo Chi Sing. Applicants and Applicants Attorney thank the Examiner for granting this interview. Possible claim amendments and the cited prior art references were discussed as stated below.

Double Patenting Rejection

Claims 1, 15, and 16 stand rejected under the judicially created doctrine of obviousness-type double patenting. These rejections are respectfully traversed.

"In determining whether a nonstatutory basis exists for a double patenting rejection, the first questions to be asked is -- does any claim in the application define an invention that is merely an obvious variation of an invention claimed in the patent? ... Obviousness-type double patenting requires rejection of an application claim when the claimed subject matter is **not patentably distinct** from the subject matter claimed in a commonly owned patent." MPEP § 804(II)(B)(1).

Claims 1, 15, and 16 read as follows:

> Claim 1. A biocompatible, hemostatic, cross-linked gelatin composition comprising a cross-linked gelatin and a sufficient amount of a wetting agent solution to permit uniform wetting of the gelatin in the presence of an aqueous solution, wherein the wetting agent solution is selected from the group consisting of polyoxyalkylenes, ether capped polyoxyalkylenes, ester capped polyoxyalkylenes, sorbitan esters, phosphatides, alkyl amines, glycerin, polymers, and surfactants.
>
> Claim 15. The biocompatible, hemostatic sponge of Claim 1, wherein the gelatin is sterilized and packaged for use in surgical procedures.
>
> Claim 16. A kit of parts for preparing a biocompatible, hemostatic cross-linked gelatin composition comprising a syringe and a non-hydrated pledget, said pledget consisting of cross-linked gelatin and wetting agent.

A. Claims 1, 15 and 16 stand "rejected under the judicially created doctrine of obviousness-type double patenting as being [allegedly] unpatentable over claim 8 of U.S. Patent No. 6,162,192, now on US '192, in view of US 6,063,061 for Wallace et. al." This rejection is respectfully traversed.

The office action states:

> "The US '192 patent claims composition comprising syringe and pledget and hydrating agent. The difference between the present claims and the previously issued conflicted claim is that the issued claim does not teach the sterilized packaged composition, or the pledget made of crosslinked gelatin."

Claim 8 of the '192 patent reads:

> "A system for facilitating hemostasis of a puncture in the wall of a blood vessel, the system comprising:
>
> a tract dilator having a lumen for allowing the tract dilator to be passed over a guidewire;
>
> an introducer having a lumen for allowing the introducer to be passed over the guidewire, the introducer lumen including a staging chamber configured to receive an absorbable sponge pledget and a delivery chamber;
>
> a plunger having a lumen for allowing the plunger to be passed over the guidewire, the plunger insertable into the introducer for ejection of the pledget from the delivery chamber into a patient to seal a puncture in a blood vessel wall;
>
> a proximal end of the introducer having a luer fitting for connection to a syringe for hydrating the absorbable sponge pledget and injecting the pledget from the introducer into the delivery chamber."

Applicant is unclear why the Examiner would assert an obviousness-type double patenting between Claims 1, 15, and 16 of the claimed invention and Claim 8 of the '192 patent. Claims 1, 15, and 16 are clearly patentably distinct from the subject matter claimed in '192. In fact, Claim 8 of the '192 patent does not claim a "composition comprising syringe and pledget and hydrating agent" as alleged by the Examiner. It is respectfully requested that this rejection be withdrawn.

B. Claims 1, 15 and 16 stand "rejected under the judicially created doctrine of obviousness-type double patenting as being [allegedly] unpatentable over claims 6-18 of U.S. Patent No. 6,200,328, now on US '328, in view of US 6,063,061 for Wallace et. al." Claims 6 and 9 are independent claims. This rejection is respectfully traversed.

The office action states that "US '328 claims system, reads on kit, comprising pledget and hydrating fluid and syringe."

Independent Claims 6 and 9 of '328 reads:

6. A system for preparing and delivering a hydrated sponge to a cannula for delivery to tissue, the system comprising:

an adaptor having a tapered lumen allowing passage of fluid through the adaptor, the lumen tapering from a first diameter at a first end to a second diameter at a second end which is smaller than the first diameter; and

a trail staging chamber removably connectable to the second end of the adaptor and having a lumen with a substantially constant diameter which is equal to or less than the second diameter of the adaptor lumen.

9. A method of facilitating hemostasis of a puncture wound by injecting a sponge through a cannula into the puncture wound, the method comprising:

inserting a pledget of a sponge into an adaptor having a tapered lumen;

connecting the adapter to a transparent visualization chamber and injecting the pledget from the adaptor into the visualization chamber;

visually inspecting the pledget within the visualization chamber to determine a condition of the pledget;

connecting the visualization chamber to a cannula; and

delivering the pledget through the cannula to facilitate hemostasis of a puncture wound.

Applicant is unclear why the Examiner would assert an obviousness-type double patenting between Claims 1, 15, and 16 of the claimed invention and Claims 6-18 of the '328 patent. It is clear that Claims 1, 15, and 16 are patentably distinct from the subject matter claimed in '328. In fact, independent Claims 6 and 9 of the '328 patent do not even claim a "system, reads on kit, comprising pledget and hydrating fluid and syringe" as alleged by the Examiner. It is respectfully requested that this rejection be withdrawn.

C. Claims 1, 15, and 16 stand "rejected under the judicially created doctrine of obviousness-type double patenting as being [allegedly] unpatentable over claims 1-5, 12-16 of U.S. Patent

No. 6,440,151, now on US '151, in view of US 6,063,061 for Wallace et. al." Claims 1 and 12 are independent claims. This rejection is respectfully traversed.

The office action states that "US '151 claims system, reads on kit, comprising pledget and hydrating fluid and syringe."

Independent Claims 1 and 12 state:

> 1. A system for facilitating hemostasis by delivery of a hydrated sponge pledget, the system comprising:
>
> a cannula for delivering the sponge in a hydrated state;
>
> an adaptor connectable to the cannula for hydrating and delivering the sponge to the cannula, the adaptor having a tapered lumen with a large diameter end and a small diameter end, wherein the small diameter end is connectable to the cannula; and
>
> a syringe for injecting fluid into the adaptor to hydrate the sponge within the adaptor.
>
> 12. A system for delivering a beneficial agent to a patient with an absorbable sponge, the system comprising:
>
> a sponge including an anti-cancer agent;
>
> a cannula for delivering the sponge in a hydrated state;
>
> an adaptor connectable to the cannula for hydrating and delivering the sponge to the cannula; and
>
> a syringe for injecting fluid into the adaptor to hydrated the sponge within the adaptor.

Applicant is unclear why the Examiner would assert an obviousness-type double patenting between Claims 1, 15, and 16 of the claimed invention and Claims 1-5, 12-16 of the '151 patent. It is clear that Claims 1, 15, and 16 are patentably distinct from the subject matter claimed in '151. In fact, independent Claims 1 and 12 of the '151 patent do not even claim a "system, reads

on kit, comprising pledget and hydrating fluid and syringe" as alleged by the Examiner. It is respectfully requested that this rejection be withdrawn.

D. Claims 1, 15, and 16 stand "rejected under the judicially created doctrine of obviousness-type double patenting as being [allegedly] unpatentable over claims 1-5, 12-16 of U.S. Patent No. 6,527,734, now on US '734, in view of US 6,063,061 for Wallace et. al." Claim 1 is an independent claim. This rejection is respectfully traversed.

The office action states that "US '734 claims system, reads on kit, comprising pledget and hydrating fluid and syringe."

Claim 1 of the '734 patent states:

> 1. A device for facilitating hemostasis of a puncture in the wall of a blood vessel, the device comprising:
>
> an introducer for compressing a sponge pledget for delivery into a patient to seal the puncture, the introducer including a staging chamber with a first diameter configured to receive the sponge pledget, a delivery chamber with a second diameter smaller than the first diameter, and a tapered section between the staging chamber and the delivery chamber for compressing the pledget, wherein the introducer is a two part system having separate staging and delivery chambers; and
>
> a pusher insertable into the introducer for ejection of the pledget from the delivery chamber into a patient to seal the puncture in the blood vessel wall.

Applicant is unclear why the Examiner would assert an obviousness-type double patenting between Claims 1, 15, and 16 of the claimed invention and Claims 1-5, 12-16 of the '734 patent. It is clear that Claims 1, 15, and 16 are patentably distinct from the subject matter claimed in '734. In fact, independent Claim 1 of the '734 patent does not even claim a "system, reads on kit, comprising pledget and hydrating fluid and syringe" as alleged by the Examiner. It is respectfully requested that this rejection be withdrawn.

E. Claims 1, 15, and 16 stand "rejected under the judicially created doctrine of obviousness-type double patenting as being [allegedly] unpatentable over claims 8-22 of U.S. Patent No. 6,540,735, now on US '735, in view of US 6,063,061 for Wallace et. al." Claims 8, 15, 17 are independent claims. This rejection is respectfully traversed.

The office action states that "US '735 claims system, reads on kit, comprising pledget and hydrating fluid and syringe."

Independent Claims 8, 15, and 17 read:

> 8. A device for facilitating hemostasis of a puncture in the wall of a blood vessel, the device comprising:
>
> a delivery cannula for delivery of a sponge pledget into a patient to seal a puncture;
>
> a pusher positioned in a proximal end of the delivery cannula for ejection of the pledget from the delivery cannula into the patient to seal the puncture; and
>
> a staging chamber having a first end removably connectable to a distal end of the delivery cannula for hydrating the sponge pledget and delivering the sponge pledget to the delivery cannula, the staging chamber having a lumen diameter which is larger than a lumen diameter of the delivery cannula.
>
> 15. A staging system for hydrating a sponge pledget, the system comprising:
>
> a staging chamber having an open lumen with a tapered section at a first end; and
>
> a connector attachable to a second end of the staging chamber for connecting a syringe to the staging chamber, the connector comprising:
>
> a connector body having a central lumen, a first end for connection to the staging chamber, and a second end for connection to a syringe;
>
> a releaseable coupling for coupling the first end of the connector body to the staging chamber; and
>
> a sealing mechanism for forming a substantially fluid tight seal between the first end of the connector and the staging chamber.

17. A device for facilitating hemostasis of a puncture in the wall of a blood vessel, the device comprising:

a delivery cannula for delivery of a sponge pledget into a patient to seal a puncture;

a pusher positioned in a proximal end of the delivery cannula for ejection of the pledget from the delivery cannula into the patient to seal the puncture; and

a staging chamber having a first end removably connectable to the delivery cannula, the staging chamber having a valve with a first position for hydrating the sponge pledget and a second position for delivering the sponge pledget to the delivery cannula, the staging chamber having a lumen diameter which is larger than a lumen diameter of the delivery cannula.

Applicant is unclear why the Examiner would assert an obviousness-type double patenting between Claims 1, 15, and 16 of the claimed invention and Claims 8-22 of the '735 patent. It is clear that Claims 1, 15, and 16 are patentably distinct from the subject matter claimed in '735. In fact, independent Claims 8, 15, and 17 of the '735 patent does not even claim a "system, reads on kit, comprising pledget and hydrating fluid and syringe" as alleged by the Examiner. It is respectfully requested that this rejection be withdrawn.

F. Claims 1, 15, and 16 stand "provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being [allegedly] unpatentable over claims 8-14, 17-22 of copending Application No. 10/366,752 in view of US 6,063,061 for Wallace et. al." This rejection is respectfully traversed. Claims 1-22 of copending Application 10/366,752 were cancelled thus rendering this rejection moot. It is respectfully requested that this rejection be withdrawn.

Specification

The Office Action states:

> "The use of the trademark "Gelfoam", "Pluronic", "Tween", "Brij", "Myrj", "UCC Carbowax", "Span" and "PGE" have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology. The trademarks should be identified by capitalizing each letter of the mark in bracket or include the proper trademark symbol such as ™ or ®."

The specification has been amended to include the trademark symbol ™ with the above-referenced trademarks. It is respectfully requested that this objection be withdrawn.

Claims 1-5 and 17 Rejection – 35 USC §112

Claims 1-15 and 17 stand rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. "The amendment to claims 1 and 5 to recite the wetting agent as a 'liquid' introduced new matter because nowhere in the specification applicant has disclosed 'liquid wetting agent'". This rejection is respectfully traversed.

The specification discloses the use of wetting agent solutions on page 19. It is respectfully asserted that a solution implies a liquid and vice versa. However, Claims 1 and 5 have been amended to recite "wetting agent solution" rather than "liquid wetting agent" to closer mirror the specification. Thus, it is respectfully requested that this rejection be withdrawn.

Claims 1 and 16 – The First 35 USC §102 Rejection

Claims 1, 15, and 16 stand rejected under 35 U.S.C. 102(e) as being allegedly anticipated by US 6,063,061 (Wallace). Claims 1 and 16 are independent claims. This rejection is respectfully traversed.

According to the M.P.E.P., a claim is anticipated under 35 U.S.C. § 102(a), (b) and (e) only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.[1]

The office action states:

> "The present claim 1 recites composition comprising cross-linked gelatin and wetting agent. ... Claim 16 recites kit comprising syringe, non-hydrated crosslinked gelatin and hydrating agent.
>
> US '061 disclosed a biocompatible hemostatic composition comprising non-hydrated cross-linked gelatin and hydrating agent (col. 3, lines 4-6, 43, 67; col. 4, lines 11-12, 41-42; col. 5, line 40; col. 8). The composition can be in the form of sterile packaged kit comprising the non-hydrated gelatin and the hydrating agent that applied through a syringe (col. 5, lines 6-10, 25-35; col. 8, lines 32-36)."

Applicant respectfully disagrees for the reasons, among others, discussed below.

Claim 1

Amended Claims 1 and 5 provide for:

> 1. A biocompatible, hemostatic, cross-linked gelatin composition comprising a cross-linked gelatin and a sufficient amount of wetting agent solution to permit uniform wetting of the gelatin in the presence of an aqueous solution, wherein the wetting agent solution is selected from the group consisting of polyoxyalkylenes, ether capped polyoxyalkylenes, ester capped polyoxyalkylenes, sorbitan esters, phosphatides, alkyl amines, glycerin, polymers, and surfactants.
>
> 16. A kit of parts for preparing a biocompatible, hemostatic cross-linked gelatin composition comprising a syringe and a non-hydrated pledget, said pledget consisting of cross-linked gelatin and wetting agent.

Wallace discloses the use of "cross-linked gels ... applied to target sites in a patient's body by extruding the gel through an orifice at the target site" (Abstract). Wallace further provides for "kits comprising any of the hydrated or non-hydrated gel materials. ... When the gel material is non-hydrated, the kit may optionally include a separate container with a suitable

[1] Manual of Patent Examining Procedure (MPEP) § 2131. See also *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

aqueous buffer for hydration." (col. 8, lines 22-36). Thus, Wallace discloses the use of cross-linked gels, rather than pledgets, to extrude at a target site. Furthermore, the "aqueous buffer for hydration" is contained in a separate container from the gel and not contained within the non-hydrated gel.

In the interview with the Examiner, she requested that the wetting agents be specified in Claim 1 to overcome Wallace as water or blood may also be viewed as a wetting agent. Claim 1 has been amended to specify the wetting agents.

Furthermore, the Examiner cited Col. 8, lines 21-37 as reading on Claim 16. Applicants respectfully disagree. Wallace discloses the use of a non-hydrated gel rather than a pledget. Futhermore, the wetting agent is not incoporated into the non-hydrated gel. Rahter, the "aqueous buffer for hydration" is contained in a separate container from the gel. Thus, Wallace does not provide for a kit "comprising a syringe and a non-hydrated pledget, said pledget consisting of cross-linked gelatin and wetting agent" as claimed in Claim 16.

Accordingly, since each and every element as set forth in Claims 1 and 16 are not found, either expressly or inherently described, in Wallace, it can not be said to anticipate the present invention. Thus, it is respectfully requested that this rejection be withdrawn.

Claims 1 and 5 – The Second 35 USC §102 Rejection

Claims 1-6, 8-13, 15, and 17 stand rejected under 35 U.S.C. 102(e) as being allegedly anticipated by US PGPB 2002/0042378 (the '378 application). Claims 1 and 5 are independent claims. This rejection is respectfully traversed.

The office action states:

> "The present claim 1 recites composition comprising cross-linked gelatin and wetting agent. The claim recites the amount of wetting agent intended to permit wetting of gelatin in the presence of an aqueous solution. . . . claim 5 recites method for decreasing the hydration time of cross-linked gelatin composition comprises incorporating wetting agent with the gelatin prior to its hydration. . . .

> PGPB '378 disclosed hemoactive material or composition that is suitable for inhibiting bleeding, i.e. hemostatic, and are delivered to the target region in the tissue subject to bleeding (page 2: 0012; page 5:0039). The material comprises cross-linked biologically compatible polymer, non cross-linked biologically compatible polymer, and plasticizer (abstract; page 2:0016). The most preferred cross-linked polymer is gelatin (page 3:0031; page 5: example 2). The non cross-linked polymers include cellulose derivatives, polyvinyl polymers, and polyoxyethylenes; and the plasticizers include polyethylene glycol and sorbitol (page 2: 0016, 0018), all disclosed by applicant in the first full paragraph of page 9 of the instant specification as wetting agents. . . . Decreasing the hydration time of the cross-linked gelatin that [is] claimed in claim 5 is inherent in the material of the reference that comprises cross-linked gelatin and polyethylene glycol, and that has the wetting agent incorporated with the cross-linked gelatin prior to use and hydration."

Applicants respectfully disagree for the reasons, among others, discussed below.

> Amended Claims 1 and 5 provide for:
>
> 1. A biocompatible, hemostatic, cross-linked gelatin composition comprising a cross-linked gelatin and a sufficient amount of wetting agent solution to permit uniform wetting of the gelatin in the presence of an aqueous solution, wherein the wetting agent solution is selected from the group consisting of polyoxyalkylenes, ether capped polyoxyalkylenes, ester capped polyoxyalkylenes, sorbitan esters, phosphatides, alkyl amines, glycerin, polymers, and surfactants.
>
> 5. A method for decreasing the hydration time of a hemostatic cross linked gelatin composition which method comprises, prior to hydration of said cross-linked gelatin composition, incorporating a biocompatible wetting agent solution with said cross-linked gelatin, wherein the wetting agent solution is selected from the group consisting of polyoxyalkylenes, ether capped polyoxyalkylenes, ester capped polyoxyalkylenes, sorbitan esters, phosphatides, alkyl amines, glycerin, polymers, and surfactants.

Amended Claims 1 and 5 provide for the use of a wetting agent **solution**.

The '378 application states that the "cross-linked polymer is dispersed in a dried matrix of the non cross-linked polymer." (page 1, 0012). This is further stated throughout the specification of the '378 application and also in Claim 1 which states "the cross-linked polymer is dispersed in a **dried** matrix of the non-cross-linked polymer" and Claim 2 which states "**dry**, cross-linked gelatin polymer particles dispersed in the dry non-cross-linked gelatin matrix." (page 7, Claim 1 and 2).

Thus, the '378 application teaches dispersing the non cross-linked polymer with the cross-linked polymer when both are in the dry phases and does not teach "a sufficient amount of a wetting agent **solution**" as provided for in Claim 1 and similarly in Claim 5.

Accordingly, since each and every element as set forth in Claims 1 and 5 are not found, either expressly or inherently described, in the '378 application, it can not be said to anticipate the present invention. Thus, it is respectfully requested that this rejection be withdrawn.

Dependent Claims

The argument set forth above is equally applicable here. The base claims being allowable, the dependent claims must also be allowable.

In view of the foregoing, it is respectfully asserted that the claims are now in condition for allowance.

Request for Allowance

It is believed that this Response places the above-identified patent application into condition for allowance. Early favorable consideration of this application is earnestly solicited.

Applicant and Applicant's Attorney again thanks the Examiner for her help with the prosecution of this application. It is respectfully requested that the Examiner call the Applicant's Attorney for an interview to expedite the prosecution of this application should a Notice of Allowance not result from this Amendment and Response.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. Please charge any additional required fee or credit any overpayment not otherwise paid or credited to our deposit account No. 50-1698.

Respectfully submitted,
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Dated: December 3, 2004

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